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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

By: Robert J. Hariri

Confirmation No.: 2020

Serial No.: 10,779,369

Art Unit: 1632

Filed: February 13, 2004

Examiner: To be Assigned

For: USE OF UMBILICAL CORD BLOOD TO
TREAT INDIVIDUALS HAVING A
DISEASE, DISORDER OR CONDITION

Attorney Docket No.: 9516-141-999
(CAM:) (501872-999140)

INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

In accordance with the duty of disclosure provisions of 37 C.F.R. §1.56, there is hereby provided certain information which the Examiner may consider material to the examination of the subject U.S. patent application. It is requested that the Examiner make this information of record if it is deemed material to the examination of the application.

1. Enclosures accompanying this Information Disclosure Statement are:
 - 1a. ☒ A list of all patents, publications, applications, or other information submitted for consideration by the office.
 - 1b. A legible copy of :
 - ☒ Each U.S. patent application publication and foreign patent;
 - ☒ Each publication or that portion which caused it to be listed on the PTO-1449;
 - ☒ For each cited pending U.S. application, the application specification including the claims, and any drawing of the application, or portion of the application which caused it to be listed on the PTO-1449 including any claims directed to that portion;
 - ☒ all other information or portion which caused it to be listed on the PTO-1449.
 - 1c. ☐ An English language copy of search report(s) from a counterpart foreign application or PCT International Search Report.
 - 1d. ☐ Explanations of relevancy (ATTACHMENT 1(d), hereto) or English language abstracts of the non-English language publications.
2. ☒ This Information Disclosure Statement is filed under 37 C.F.R. §1.97(b):
 - ☐ Within three months of the filing date of a national application other than a continued prosecution application under §1.53(d);
 - ☐ Within three months of the date of entry of the national stage as set forth in §1.491 in an international application;

- ☒ Before the mailing of the first Office action on the merits;
- ☐ Before the mailing of a first Office action after the filing of a request for continued examination under §1.114.

3. ☐ This Information Disclosure Statement is filed under 37 C.F.R. §1.97(c) after the period specified in 37 C.F.R. §1.97(b), but before the mailing date of any of a final action under 37 C.F.R. §1.113, a notice of allowance under 37 C.F.R. §1.311 or an action that otherwise closes prosecution in the application.

(Check either Item 3a or 3b)

- 3a. ☐ The Certification Statement in Item 5 below is applicable. Accordingly, no fee is required.
- 3b. ☐ The \$180.00 fee set forth in 37 C.F.R. §1.17(p) in accordance with 37 C.F.R. §1.97(c) is:
- ☐ enclosed
- ☐ to be charged to Jones Day Deposit Account No. 50-3013.

(Item 3b to be checked if any reference known for more than 3 months)

4. ☐ This Information Disclosure Statement is filed under 37 C.F.R. §1.97(d) after the period specified in 37 C.F.R. §1.97(c), but on or before the date of payment of the issue fee.

The Certification Statement in Item 5 below is applicable.

The \$180.00 fee set forth in 37 C.F.R. §1.17(p) is:

- ☐ enclosed.
- ☐ to be charged to Jones Day Deposit Account No. 50-3013

5. ☐ Certification Statement (applicable if Item 3a or Item 4 is checked)

(Check either Item 5a or 5b)

- 5a. ☐ In accordance with 37 C.F.R. §1.97(e)(1), it is certified that each item of information contained in this Information Disclosure Statement was first cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement.
- 5b. ☐ Each item of information contained in this information disclosure statement was cited in a communication from a foreign patent office in a counterpart application, and the communication was not **received** by any individual designated in 37 C.F.R. §1.56(c) more than thirty days prior to the filing of this information disclosure statement.
- 5c. ☐ Pursuant to 37 C.F.R. §1.704(d), each item of information contained in this information disclosure statement was cited in a communication from a foreign patent office in a counterpart application, and the communication was not **received** by any individual designated in 37 C.F.R. §1.56(c) more than thirty days prior to the filing of this information disclosure statement.
6. ☐ This application is a continuation application under 37 C.F.R. §1.60 or §1.53(b) or (d).

(Check appropriate Items 6a, 6b and/or 6c)

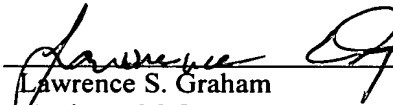
- 6a. ☐ A Petition to Withdraw from issue under 37 C.F.R. §1.313(b)(5) is concurrently filed herewith.
- 6b. ☐ Copies of publications listed on Form PTO-1449 from prior application Serial No. , filed on , of which this application claims priority under 35 U.S.C. §120, are not being submitted pursuant to 37 C.F.R. §1.98(d).
- 6c. ☐ Copies of the publications listed on Form PTO-1449 were not previously cited in prior application Serial No. , filed on , and are provided herewith.
7. ☐ This is a Supplemental Information Disclosure Statement.
- 7a. ☐ This Supplemental Information Disclosure Statement under 37 C.F.R. §1.97(f) supplements the Information Disclosure Statement filed on . A bona fide attempt was made to comply with 37 C.F.R. §1.98, but inadvertent omissions were made. These omissions have been corrected herein. Accordingly, additional time is requested so that this Supplemental Information Disclosure Statement can be considered as if properly filed on .
8. ☐ In accordance with 37 C.F.R. §1.98, a concise explanation of what is presently understood to be the relevance of each non-English language publication is:

(Check Item 8a, 8b, or 8c)

- 8a. ☐ satisfied because all non-English language publications were cited on the enclosed English language copy of the PCT International Search Report or the search report from a counterpart foreign application indicating the degree of relevance found by the foreign office.
- 8b. ☐ set forth in the application.
- 8c. ☐ enclosed as an attachment hereto.
9. ☒ The Commissioner is authorized to charge any additional fee required or credit any overpayment for this Information Disclosure Statement and/or Petition to Jones Day Deposit Account No. 50-3013.
10. ☒ No admission is made that the information cited in this Statement is, or is considered to be, material to patentability nor a representation that a search has been made (other than a search report of a foreign counterpart application or PCT International Search Report if submitted herewith). 37 C.F.R. §§1.97(g) and (h).

Respectfully submitted,

Date: January 26, 2005


for Lawrence S. Graham
Anthony M. Insogna

35,203
49,020
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LIST OF REFERENCES CITED BY APPLICANT

(Use several sheets if necessary)

ATTY DOCKET NO.
9516-141-999
(501872-999140)

APPLICATION NO
10/779,369

APPLICANT
HARIRI, Robert J.

CONFIRMATION NO.:
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FILING DATE
February 13, 2004

ART UNIT:
1632

U.S. PATENT DOCUMENTS

*EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	A1	2001/0038836	11/08/01	During et al.	424	93.7	
	A2	2002/0028510	03/07/02	Sanberg et al.	435	368	
	A3	2002/0086005	07/04/02	Chiu et al.	424	93.21	
	A4	5,004,681	04/02/91	Boyse et al.	435	2	
	A5	5,192,553	03/09/93	Boyse et al.	424	529	
	A6	5,372,581	12/13/94	Anderson	604	32	
	A7	5,415,665	05/16/95	Hessel et al.	606	120	
	A8	5,643,741	07/01/97	Tsukamoto et al.	435	7.24	
	A9	5,646,043	07/08/97	Emerson et al.	435	3773	
	A10	5,654,186	08/05/97	Cerami et al.	435	324	
	A11	5,665,557	09/09/97	Murray et al.	435	7.24	
	A12	5,670,147	09/23/97	Emerson et al.	424	93.1	
	A13	5,670,351	09/23/97	Emerson et al.	435	440	
	A14	5,673,346	09/30/97	Srou et al.	385	60	
	A15	5,716,827	02/10/98	Tsukamoto	435	325	
	A16	5,733,541	03/31/98	Taichman et al.	424	93.1	
	A17	5,750,397	05/12/98	Tsukamoto et al.	435	372	
	A18	5,763,266	06/09/98	Palsson et al.	435	289.1	
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	A20	5,827,742	10/27/98	Scadden	435	377	
	A21	5,858,782	01/12/99	Long et al.	435	372	
	A22	5,861,315	01/19/99	Nakahata	435	384	
	A23	5,874,301	02/23/99	Keller et al.	435	325	
	A24	5,914,268	06/22/99	Keller et al.	435	325	
	A25	6,030,836	02/29/00	Thiede	435	347	
	A26	6,102,871	08/15/00	Coe	600	575	
	A27	6,110,739	08/29/00	Keller et al.	435	325	
	A28	6,179,819	01/30/01	Haswell	604	356	
	A29	6,224,860	05/01/01	Brown	424	93.7	
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	A31	6,306,575	10/23/01	Thomas et al.	435	2	
	A32	6,326,198	12/04/01	Emerson et al.	435	373	
	A33	6,335,195	01/01/02	Rodgers et al.	435	377	
	A34	6,337,387	01/08/02	Sakano et al.	530	350	
	A35	6,338,942	01/15/02	Kraus et al.	435	2	

FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
							YES	NO
	B1	WO 99/64566	12/30/99	PCT				

OTHER REFERENCES (Including Author, Title, Date, Pertinent Pages, Etc.)

C1	Chen, R. & Ende, N., "The Potential for the Use of Mononuclear Cells From Human Umbilical Cord in the Treatment of Amyotrophic Lateral Sclerosis in SOD1 Mice," <i>Journal of Medicine</i> 31(1-2):21-30 (2000)
C2	Ende, M. et al., "Hemapoetic Transplantation By Means of Fetal (Cord) Blood: A New Method," <i>Va Med Mon</i> 99:276-280 (1972)
C3	Ende N. "Collection of Umbilical Cord Blood for Transplantation," <i>Blood</i> 80(6):1623-1624 (1992)
C4	Ende, "The Feasibility of Using Blood Bank Stored (4°C) Cord Blood, Unmatched for HLA for Marrow Transplantation," <i>Am. J. Clin. Pathol.</i> 111:773-781 (1999)
C5	Ende et al., "Human Umbilical Cord Blood Effect On Sod Mice (Amyotrophic Lateral Sclerosis)," <i>Life Sci.</i> 67:53-59 (2000)
C6	Ende et al., "Pooled Umbilical Cord Blood as a Possible Universal Donor for Marrow Reconstitution and Use in Nuclear Accidents," <i>Life Sci.</i> 69:1531-1539 (2001)
C7	Ende, N. & Chen R., "Human Umbilical Cord Blood Cells Ameliorate Huntington's Disease in Transgenic Mice," <i>Journal of Medicine</i> 32(3-4):231-240 (2001)
C8	Ende, N. & Chen R., "Human Umbilical Cord Blood Cells Ameliorate Alzheimer's Disease in Transgenic Mice," <i>Journal of Medicine</i> 32(3-4):241-247 (2001)
C9	Ende, N. & Chen R., "Parkinson's Disease Mice and Human Umbilical Cord Blood," <i>Journal of Medicine</i> 33(1-4):173-180 (2002)
C10	Ende, N., "Berashis Cells in Human Umbilical Cord Blood Vs. Embryonic Stem Cells," <i>Journal of Medicine</i> 33(1-4):167-171 (2002)
C11	Rameshwar et al., "Endogenous Hematopoietic Reconstitution Induced by Human Umbilical Cord Blood Cells in Immunocompromised Mice: Implications for Adoptive Therapy," <i>Experimental Hematology</i> 27:176-185 (1999)
C12	Viacord, Umbilical Cord Blood Can Save Lives (Information brochure), Boston: ViaCell CENTR-BRO R1 10/01 (2001)
C13	Wang et al., "Enhanced Recovery of Hemapoietic Progenitor and Stem Cells from Cultivated, Postpartum Human Placenta," <i>Blood</i> 68:183, abstract 769 (2001)
C14	Ashihara et al., "Successful Peripheral Blood Stem Cell Transplantation for Myelodysplastic Syndrome," <i>Bone Marrow Transplantation</i> 24(12):1343-1345 (1999)
C15	Cardoso et al., "Release From Quiescence of CD34+ CD38- Human Umbilical Cord Blood Cells Reveals Their Potentiality to Engraft Adults," <i>Proc Natl Acad Sci USA</i> 90(18):8707-8711 (1993)
C16	Gluckman et al., "Cord Blood Hematopoietic Stem Cells: Biology and Transplantation," In: <i>Hematology, American Society of Hematology Education program Book</i> , 1998, p.1-14
C17	Gluckman et al., "Results of Unrelated Umbilical Cord Blood Hematopoietic Stem Cell Transplant," <i>Transfusion Clinique et Biologique</i> 8(3):146-154 (2001)
C18	Hows "Status of Umbilical Cord Blood Transplantation in the Year 2001," <i>J Clin Pathol</i> 54(6):428-434 (2001)
C19	Kondo et al., "Reduced Interferon Gamma Production by Antigen-Stimulated Cord Blood Mononuclear Cells is a Risk Factor of Allergic Disorders - 6-Year Follow-up Study," <i>Clin Exp Allergy</i> 28(11):1340-1344 (1998)
C20	Korbling et al., "Peripheral Blood Stem Cell Versus Bone Marrow Allotransplantation: Does the Source of Hematopoietic Stem Cells Matter?" <i>Blood</i> 98(10):2900-2908 (2001)
C21	Sakabe et al., "Functional Differences Between Subpopulations of Mobilized Peripheral Blood-Derived CD34+ Cells Expressing Different Levels of HLA-DR, CD33, CD38 and c-kit Antigens," <i>Stem Cells</i> 15(11):73-81 (1997)
C22	Vilmer et al., "HLA-Mismatched Cord Blood Transplantation: Immunological Studies," <i>Blood Cells</i> 20(2-3):242-244 (1994)

EXAMINER

DATE CONSIDERED

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.